IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Spectrum Pharmaceuticals, Inc. and **University of Strathclyde,** Plaintiffs, v. **Innopharma, Inc., Mylan Teoranta, Mylan Institutional LLC,** and **Mylan Institutional, Inc.,** Defendants.	Civil Action No. 12-260-RGA-CJB

MEMORANDUM ORDER

Before the Court is Defendants' Objections to the Magistrate Judge's July 3, 2014 Report & Recommendation (D.I. 183) and Plaintiffs' Objections to the Report and Recommendation Regarding Construction of the Final Term of Claim 5 (D.I. 184), as well as the parties' respective responses. (D.I. 187, 188). The Report and Recommendation on Claim Construction (D.I. 180) construed two groups of terms: the "mixture" and "percentage" terms as well as the final portion of claim 5. Defendants object to the Magistrate Judge's construction of the "mixture" and "percentage" terms and Plaintiffs object to the Magistrate Judge's construction of the final portion of claim 5.

The "mixture" and "percentage" terms have little to do with the construction of those actual terms, but whether the claims contain an implicit ceiling of 98% on the amount of the (6S) diastereoisomer in the mixture of the (6S) and (6R) diastereoisomers. The Magistrate Judge found that they did not. Defendants contend that they do. The claims do not contain any upper

limit on the amount of the (6S) diastereoisomer, claiming only a floor of 92% or 95%. Defendants contend that there is an implicit ceiling of 98% due to the applicant's efforts to overcome a rejection by the Examiner. During prosecution, the Examiner issued a rejection of one of the claims on the ground that the patent did not enable mixtures containing "greater than 95%" of the (6S) diastereoisomer. In response, the applicants submitted a declaration showing purity levels up to 98%. Because the applicants did not demonstrate purity levels over 98%, Defendants contend that levels over 98% are not enabled, and therefore the claims should be construed to be limited to 98%.

As an initial matter, Defendants do not address why I even need consider this argument. Generally, enablement is not at issue during claim construction, especially, as here, where the claims are easily understood. However, I will entertain Defendants' arguments. Defendants specifically refer to *Biogen Idec. Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090 (Fed. Cir. 2013), for the proposition that a patent applicant's arguments as to why claims are enabled define the scope of the invention. In *Biogen*, the Examiner issued an enablement rejection because the claim term "anti-CD20 antibodies" was only enabled for Rituxan. In response, the applicant stated that "even though antibodies directed to the same antigen might have different affinities and functional characteristics, one of skill in the art could readily identify an antibody that binds to CD20 with similar affinity and specificity as does RITUXAN® using techniques that are well known in the art." *Biogen*, 713 F.3d at 1093. The district court therefore construed the term "anti-CD20 antibodies" as "rituximab and antibodies that bind to the same epitope of the CD20

antigen with similar affinity and specificity as rituximab."[1] *Id.* at 1094. Because the accused product bound to another epitope,[2] the parties stipulated to noninfringement and appealed. *Id.* The Federal Circuit concluded that the claims had been limited because there was a clear and unmistakable disclaimer "of antibodies that do not have a similar affinity and specificity for the specific epitope to which Rituxan® binds." *Id.* at 1096.

Here, I do not believe that there was a clear and unmistakable disclaimer of purity levels above 98%. The applicants, when questioned whether the claims were enabled for purity levels greater than 95%, demonstrated that those levels were enabled. Nothing in the declaration demonstrated a clear and unmistakable disclaimer as was present in *Biogen*. In *Biogen*, the question of enablement was one of kind. Simply put, the prosecution history in *Biogen* only enabled certain types of antibodies. Other types of anitbodies were therefore disclaimed. Here, the question of enablement is one of amount. The applicants demonstrated that the claimed invention could produce results within a claimed range. Whether the range is fully enabled is not an issue for claim construction because there was no disclaimer. I therefore adopt the Magistrate Judge's recommended claim construction for the "mixture" and "percentage" terms.

I next turn to Plaintiffs' objections regarding the final portion of claim 5. Claim 5 is as follows:

> A pharmaceutical composition for therapeutic use for the treatment of human beings comprising:
>
> [a] a pharmaceutically acceptable composition which is a (6S) diastereoisomer selected from the group consisting of (6S) leucovorin (5-formyl-(6S)-tetrahydrofolic acid) and pharmaceutically acceptable salts and esters of (6S) leucovorin, wherein the composition consists of a mixture of (6S) and (6R) diastereoisomers and consists of at least about 92% by weight of the (6S)

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[1] Rituxan is the trade name for rituximab.

[2] When the patent was filed it was believed that CD20 had only one epitope.

diastereoisomer, the balance of said composition consisting of the (6R) diastereoisomer; and

[b] a pharmaceutically acceptable carrier; and

[c] said composition being of a quantity at least sufficient to provide multiple doses of said mixture of (6S) and (6R) diastereoisomers in an amount of 2000 mg per dose.

(Claim 5 of '829 patent). The Magistrate Judge construed subparagraph [c] to mean that "the 'pharmaceutically acceptable composition' contains enough of the (6S)/(6R) mixture that, once the mixture is combined with the 'pharmaceutically acceptable carrier,' the resulting 'pharmaceutical composition for therapeutic use' contains, at minimum, 4000 mg of the mixture." (D.I. 180 at 28). Plaintiffs argue that this construction is incorrect because it requires a single composition to have the requisite amount of the mixture rather than allowing for aggregation of multiple, separately-packaged compositions.

Plaintiffs point to two reasons why the Magistrate Judge's claim construction was in error: first, that the Magistrate Judge used the term "consists of," when the claim is an open ended "comprising" claim; second, that the use of the term "a" composition allows for "one or more" such compositions. I do not agree that there was an error. First, the Magistrate Judge did not use the term "consists of" in the closed manner for which it is used in the patent law. The Magistrate Judge described claim 5 as "a 'composition' that 'consists of' sub-part [a]'s 'pharmaceutically acceptable composition' combined with the 'pharmaceutically acceptable carrier' of sub-part [b]." (D.I. 180 at 23). Nowhere in the report and recommendation did the Magistrate Judge imply that the claimed "pharmaceutical composition for therapeutic use" was limited to only these two ingredients. Clearly the Magistrate Judge was using the term "consisting" in the colloquial fashion, and did not give the term its specialized meaning. I

interpret the use of "consisting of" to be the same as "comprising," and find no error in the Magistrate Judge's analysis.[3]

As for Plaintiffs' second argument, it is true that the use of the term "a" refers to "one or more." Plaintiffs argue that because "a" can refer to "one or more," there might be "one or more" of the subparagraph [a] composition, and as long as the aggregate amount of the mixture meets subparagraph [c]'s requirements, the claim would be met. I disagree. Even assuming that the claim allows for more than one of the subparagraph [a] compositions, each of the subparagraph [a] compositions must meet subparagraph [c]'s requirements. The parties agree that subparagraph [c] refers to subparagraph [a]. Assuming that "said" in subparagraph [c] refers to "one or more" of the subparagraph [a] compositions, I construe subparagraph [c] to mean that each of the subparagraph [a] compositions must meet the subparagraph [c] requirements. I therefore adopt the Magistrate Judge's recommended claim construction for the final portion of claim 5.

As discussed above, I adopt the Magistrate Judge's Report and Recommendation on Claim Construction (D.I. 180) as my claim construction.

Entered this 26th day of August, 2014.

United States District Judge

[3] Plaintiffs do not successfully explain why, even assuming the Magistrate Judge used "consisting of" as though he were drafting patent claims, it would make any difference on the disputed point.